REMARKS/ARGUMENTS

Obviousness-Type Double Patenting

Claims 1-4, 14-21, 23-28, and 30-40 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 30, 32, 34-36, 38-40, and 49-66 of copending Application No. 10/795,191. Applicants believe the rejection is premature. Should any of the pending claims of copending Application No. 10/795,191 be allowed and not subject to a restriction requirement, then Applicants would be willing to consider filing a terminal disclaimer if appropriate.

Rejection Under 35 U.S.C. § 102(b) US 4,299,501 (Patil et al.)

Claims 1, 21-26, and 30-40 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by US 4,299,501 (Patil et al.). Applicants respectfully disagree. Patil et al. relates to a process for preparing semisolid dispersion which comprises circulating oil and water phases from a single vessel through a system of mixers and homogenizers (Abstract). The final product is an emulsion (column 3, line 2). These emulsions are useful as creams, jellies, ointments and the like (column 1, line 4). A pharmaceutical material is an optional ingredient which may be either dissolved in the oil phase (column 2 line 68), present in the aqueous phase (column 3 lines 7-8), or suspended in the emulsion (column 3 lines 1-2).

Applicants' claimed invention is a composition comprising an antibacterial substance dispersed in a non-aqueous carrier. Applicants' composition does not have an aqueous phase and is not an emulsion. Accordingly Applicants respectfully submit that the emulsion composition produced by the process of Patil et al. is not the same as Applicants' composition. It is important to note that if a pharmaceutical material is present in the oil phase of the Patil et al. composition, it is dissolved in the oil phase (column 2 line 68). There is no disclosure in Patil et al. of an antibacterial substance dispersed in an oil carrier. Thus, Patil et al. does not anticipate Applicants' invention. Reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b) is respectfully requested.

Rejection Under 35 U.S.C. § 103(a) US 4,299,501 (Patil et al.) in view of US 2002/0110561 (Teagarden)

Claims 2-4, 14-20, 27, and 28 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over US 4,299,501 (Patil et al.) in view of US 2002/0110561 (Teagarden). In making this rejection the Examiner states that Teagarden also discloses mono-, di-, and triglycerides of fatty acids and non-oils such as polyethylene glycol. The Examiner alleges that this reads on the definition of amphipathic oil. Applicants respectfully disagree with this statement. Polyethylene glycols are water soluble and thus are not amphipathic oils. Triglycerides are ordinary oils and fats. As anyone who has ever made a water in oil salad dressing by shaking the oil and water together knows the triglyceride oils are not readily dispersible in water. Accordingly, triglycerides are not amphipathic oils. Mono and di-glycerides are well known emulsifiers, but are not known to have the required water dispersibility and ethanol insolubility to be amphipathic oils. Teagarden does not disclose a composition of an antibacterial in a carrier containing an amphipathic oil. As set forth above the composition of Patil is an emulsion. When the emulsion of Patil is combined with composition of Teagarden the person skilled in the art would expect to obtain some type of emulsion. Applicants' inventive composition is a dispersion, not an emulsion. It is respectfully submitted that the combination of the teaching of Teagarden and Patil does not lead to Applicants' invention.

The composition of Teagarden may be administered parenterally, including intramammary infusion (paragraph 61). The composition is designed to provide release of the bioactive agent on a sustained basis (Abstract). In other words, the composition is designed to remain in place for some period of time while releasing the bioactive agent. In contrast, paragraph 61 of the present application shows that administration of the compositions of the present invention produce effective levels of the bioactive agent which then drop quickly thereby allowing short milkout times after treatment of mastitis. The person skilled in the art would expect that the combination of the Teagarden and the compositions of Patil would have the sustained release characteristics of the compositions of Teagarden, and thus would not solve the problem solved by Applicants' invention. It is respectfully submitted that the combination of the

teaching of Teagarden and Patil does not lead to a composition having the desirable characteristics of the composition of Applicants' invention.

Applicants respectfully submit that the combination of Teagarden with Patil is not appropriate. A person skilled in the art who was trying to find discover a composition which provided a short milkout time would not turn to the sustained release formulation of Teagarden as one of the components of a combination. To put it another way, the person skilled in the art would not turn to a composition which provides sustained release, and therefore longer milkout times as part of a method to achieve short milkout times.

In order to combine elements from two references to render an invention obvious, there must be some motivation that would lead the person skilled in the art to combine the elements. In KSR v. Teleflex (500 U.S. ---- (2007)) the Supreme court states:

> ... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. (Slip opinion p. 15)

Accordingly, KSR implies that there must be some reason that would have prompted a person of ordinary skill in the relevant field to take the emulsion of Patil and combine it with the composition of Teagarden. In KSR the elements being combined all related to automobile brake pedals and thus, it was proper to combine them. In this case, the compositions of Patil et al. are semisolid dispersions (column 1 lines 5-6), or emulsions (column 3 line 2), of the oil-in-water or water-in-oil type (column 2 line 56-59). The composition of Teagarden is a sustained release drug suspension. There is no motivation for a person skilled in the art to combine a semi-solid emulsion with a sustained release suspension in an attempt to create a composition having rapid dispersibility which provides short milkout times after treatment.

Reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested. Withdrawal of all rejections and timely allowance of the instant application is earnestly solicited.

Respectfully submitted,

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